underwent EVT alone, without bypass surgery. Patients were divided into two groups depending on whether or not wound blush was obtained in the angiogram obtained immediately after the procedure, SPP and the 'freedom from amputation' rate was compared between the two groups.
**Results:** Improvement of the SPP measured near the ulcer was observed after the EVT in both groups; however, the improvement was more pronounced in the WB-positive group (23.4±13.6 mmHg vs. 9.5±11.0 mmHg, P=0,001).The overall limb salvage rate was 81.7%. The limb salvage rate was significantly higher in the wound blush-positive group than in the wound blush-negative group, and remained so for at least 3 years after the EVT (96.4% vs. 56.8%, P<0.001).
**Conclusions:** Presence of wound blush after EVT is associated with higher SPP, both of which are associated with higher rates of limb salvage. Wound blush as an angiographic endpoint in EVT may be a novel predictor of limb salvage in patients with CLI.

## TCT-187

### Factors of Restenosis After Endovascular Treatment for Iliac Artery

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**Background:** The factors associated with restenosis after endovascular treatment (EVT) for iliac artery lesions in peripheral arterial disease (PAD) were not established. The aim of this study was to investigate the predictors of restenosis after EVT for iliac artery.
**Methods:** The REAL-AI (REtrospective multicenter AnaLysis of primary stenting for AortoIliac artery disease) registry was performed as a multicenter registry enrolling consecutive patients undergoing primary stenting for de novo lesion. From January 2005 to December 2009, a total of 2096 patients (2601 lesions, age: 71.3±7.5years, mean follow interval 31±15 months, claudicant: 82.2%) were enrolled. Univariate and multivariate analysis were performed to estimate the predictors of restenosis after EVT for iliac artery.
**Results:** EVT was performed for 2601 lesions (TransAtlantic Inter-Society Consensus-II (TASC-II) Type-A: 1201, B: 694, C: 311, D: 395) in PAD patients. The mean lesion length was 53±31mm. Restenosis rate was 14.1% (368 lesions), primary patency was 92.5% at 1 year. The mean term of restenosis from procedure was 810.4±548.8 days. Results of multivariate analysis were shown in the table.
**Conclusions:** We found stent fracture, low out flow and non-use of aspirin to be predictors associated with restenosis after EVT for iliac artery.

| | OR | 95% CI | P value |
|---|---|---|---|
| Age | 1.0 | 1.005-1.003 | 0.009 |
| Tall | 1.0 | 1.00-1.04 | 0.002 |
| Fracture | 13.6 | 1.67-281.28 | 0.015 |
| Dyslipidemia | 1.4 | 1.10-1.85 | 0.008 |
| Insulin | 1.5 | 1.04-2.02 | 0.029 |
| Vessel diameter | 1.1 | 0.97-1.22 | 0.180 |
| Out flow | 1.7 | 1.28-2.18 | <0.001 |
| Aspirin | 0.6 | 0.41-0.81 | 0.002 |

## TCT-188

### Efficacy of the Novel Ultrasonography "Vascular Elastography" Guided Endovascular Therapy

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**Background:** The success rate of endovascular therapy (EVT) for chronic total occlusion (CTO) of femoropopliteal arteries has improved because of devices development and the introduction of the echo guided EVT from body surface. But now this is still challenging. Elastography is a new ultrasonographic method that has been examined as a diagnostic tool for breast lesions. We applied this method to hardness measurement of CTO lesions by our original method. Our aim was to investigate the usefulness of the novel ultrasonography (US) "vascular elastography (VE)" for EVT.
**Methods:** In 516 consecutive cases which underwent EVT between April 2010 and December 2011, we focused on 56 cases of EVT for CTO of femoropopliteal arteries. We assessed the CTO lesions by duplex US and "VE" about lesion morphology with our original methods before procedure. US was performed with 8 MHz linear transducer (Aprio XG, TOSHIBA, Japan), and off-line analysis of "VE" was performed with elasto-Q (TOSHIBA, Japan). We originally categorized into five types by original VE score. Comparing investigation about procedure results was performed between hard group (H group: VE score 0-2) and soft group (S group: VE score 3-4).
**Results:** We could assess elastogram of target lesions in all cases (H group: 33 cases vs. S group: 23 cases). Cases in S group could be penetrated with hydrocoat soft guidewire (12.1% vs. 65.2%; p<0.001). Retrograde approach from popliteal artery was needed in only H group (39.1% vs. 0%; p=0.007). Operation time in H group was longer than S group (152.9±63.2min vs. 87.0±29.8min; p<0.001). In 6 cases, CTO site was assessed soft with thrombus. Therefore we successfully performed thrombectomy and distal protection preventing for distal embolism. Hard plaque (VE score 1-2) which difficultly penetrated without calcification by B mode of US could be assessed in 10 cases. In 11 cases with VE score 4, hydrophilic soft guidewire (Cruse®, Asahi Intecc Co. Ltd., Japan) could pass the lesion easily at the site of soft appearance by VE.
**Conclusions:** "Vascular Elastography" might be useful when we decide strategies and selections of device in EVT because we could assess the vascular morphology noninvasively before procedure.

## TCT-189

### Plaque Excision as a Treatment Option for Popliteal Atherosclerotic Disease: 1-Year Results from the DEFINITIVE LE Study

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**Background:** The popliteal artery is often referred to as the ″no-stent zone″ due to concern for stent fracture, kinking or occlusion secondary to the constant torsion, compression and flexion applied to the vessel. The DEFINITIVE LE study was a global study that assessed the effectiveness of atherectomy using the SilverHawk® and TurboHawkTM systems (Covidien/ev3, Plymouth, MN) for peripheral arterial disease (P.A.D.) in femoropopliteal and tibial-peroneal arteries in both claudicants and critical limb ischemia (CLI).
**Methods:** 800 patients with a total of 1023 infrainguinal lesions were enrolled in DEFINITIVE LE and underwent revascularization with atherectomy. A subset analysis was performed for all patients with lesions in the popliteal ″no-stent″ zone. Follow-up occurred at pre-discharge, 30 days, 6 months and 1 year. Endpoints were assessed by independent angiographic and duplex core laboratories and adverse events by a Clinical Events Committee. The primary endpoint for claudicants was primary patency. Secondary assessments included Rutherford Clinical Category, ankle-brachial index, the Walking Impact Questionnaire, EQ-5D and adverse events.
**Results:** Preliminary results are reported below; final results will be presented at TCT 2012. In total, 158 subjects had 162 target lesions in the popliteal artery. 70.4% (114/162) of those lesions were in claudicants. The mean lesion length was 5.8 cm and the mean baseline stenosis was 75.8%. Primary patency (PSVR ≤ 2.4) was 80.3% at 1 year. Demographics, lesion characteristics and outcomes are shown below. The bailout stent rate was 3.7% for popliteal lesions.

| Characteristic/Outcome | Popliteal only (n=158, 162 lesions) |
|---|---|
| Age (yrs) | 72.0 ± 10.9 |
| Female | 48.1% |
| Caucasian | 71.5% |
| History and risk factors | |
| Hypertension | 94.9% |
| Diabetes | 52.5% |
| Renal insufficiency | 22.8% |
| Current or former smoker | 33.5% |
| Mean lesion length (cm) | 5.8 ± 3.9 |
| Baseline diameter stenosis | 76.2% ± 18.2% |
| Post-plaque excision stenosis | 25.7% ± 14.7% |
| Device success | 71.3% |
| 1-year primary patency (PSVR 2.4) (Claudicants) | 80.4% |
| 1-year primary patency (PSVR 3.5) (Claudicants) | 81.4% |
| Freedom from amputation (CLI) | 100% |

**Conclusions:** These independent core laboratory confirmed results show that atherectomy is highly effective in the treatment of atherosclerotic lesions of the popliteal artery and can avoid the use of stents in his complex anatomic region.

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